

REMARKS

1. – 3. Restriction/Election:

The Applicants affirm the election to prosecute the invention of Group I, Claims 1-17. Consistent with the election, Claims 18-53, being withdrawn from further consideration, are hereby cancelled.

5. - 6. Objection:

The Examiner has objected to Claims 11 -17 as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. In a sincere effort to move this case to a condition for allowance, Claims 11 – 17 have been cancelled herein.

However, the Agent for the Applicants requests the Examiner's consideration of the following remarks:

Upon review of the objection, the Agent for the Applicants has reviewed the Multiple Dependent Claim Fee Calculation Sheet available from the PAIR system. The sheet indicates the application as filed was noted as having only two (2) independent claims. The Agent respectfully notes that the Application as filed had eight (8) independent claims: Claims 1, 11, 15, 18, 42, 43, 44, and 53. Because claims 11 and 15 are independent claims (11 drawn to a cell transformed with a DNA construct; 15 drawn to a transgenic plant expressing a DNA construct), they were not multiple dependent claims that improperly depended from a multiple dependent claim.

Further, in the Restriction Requirement mailed from the Patent Office on August 10, 2006 the Examiner characterized Group I, Claims 1-17 as “drawn to a **DNA** expression construct comprising a nucleic acid sequence which encodes a mutant Δ^9 -18-0-ACP desaturase of SEQ ID NO: 1, classified in class 536, subclass 23.2.”

The Agent for the Applicants respectfully submits that Group I might more properly have been characterized as:

Group I. Claims 1-17, drawn to DNA expression constructs comprising a nucleic acid sequence which encodes a mutant Δ^9 -18-0-ACP desaturase of SEQ ID NO: 1 and having specifically substituted amino acids, cells transformed with said DNA expression constructs (Claims 11-14) and transgenic plants expressing said DNA constructs (15-17).

In the restriction requirement of August 10, 2006 the Examiner did not provide reasons or examples or suggest that the invention of Claims 1-17 were "independent or distinct" nor that there would be a serious burden on the Examiner if restriction is/was not required.

Although claims 11 – 17 have been cancelled, the substance therein has been captured in newly added claims 56 – 62. In these newly added claims, claim 56 is an independent claim in Markush format. Claim 60 is also an independent claim. Because claims 56 – 62 restate the originally filed claims 11 – 17, they contain no new matter.

4. Claim Rejections – 35 USC §112 (second paragraph):

The Examiner has rejected claims 1 – 17 as being indefinite for failing to particularly point out and distinctly claim the subject matter with applicants regard as the invention. The examiner further suggests deletion of the expression "residue homologous to" and the expression "in expressible form", the former being the basis for the indefiniteness rejection and the latter being characterized as "redundant and confusing".

In response, claims 1 – 9 have been amended herein so as to comply with the Examiner's suggestion.

With respect to the suggestion that “in expressible form” is redundant and confusing, the Applicants’ Agent wishes to note that the phrase was meant to be explicative and thorough. However, in a sincere effort to move this case to a condition for allowance, the Agent has relied upon the Examiner’s statement that “if it is a DNA expression construct it is capable of expression” and deleted the phrase “in expressible form”.

The Agent for the Applicant states that all amendments to the claims made as a result of the Examiner’s rejections under 35 USC 112, second paragraph contain no new matter.

7. Claim Rejections – 35 USC §103 (a):

First, as the Examiner notes, the application under review names joint inventors. The Examiner then “presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made”. The Agent for the Applicants confirms that this is a correct assumption.

Following those remarks, the Examiner has rejected claims 1 – 10 as being unpatentable over Cahoon et al. [PNAS 94: 4872-4877, May 1997, Reference 1]. The Examiner states that “Cahoon et al. teach castor mutants or modified Δ^9 -18:0-ACP desaturase, the encoding DNA and the crystallographic model of the active sites and variants or mutants. Characterization of specific mutants at positions 114, 117, 118, 179, 181, and 188 are also taught. . . . The reference also teaches specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions . . .” Further, the Examiner states “Cahoon et al. do not teach the specifically claimed substitutions.” And, further still: “It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute parent amino acid at positions 114, 117, 118, 179, 181 & 188 with any of the remaining 19 amino acids,

make DNA constructs comprising the mutated DNA and suitably express in a host cell, and do so with a reasonable expectation of success.” The Examiner further points out that a motivation to do so is evident in the cited art.

Taking these comments together, the Agent for the Applicants concurs that the cited reference identifies residues 114, 117, 118, 179, 181 and 188 as being candidate amino acids relevant to specificity of activity of the Δ^9 -18:0-ACP desaturase of castor. The Agent further points out that the cited reference, in addition to the above residues, also identifies candidate residues 115, 180, 189, 200, 205, 206 and 207 (see figure 3) as potential candidates for mutation with the purpose of modifying the activity of the castor Δ^9 -18:0-ACP desaturase.

It is important, however, to note that the reference neither predicts nor suggests what amino acids to substitute for the native amino acids to create the mutants invented herein. A person of skill in the art would have no way of knowing what amino acids would work and which would not. There is NO suggestion that substitution of any one of these positions with any amino acid or any of the remaining 19 amino acids either singly or in combination with one another would have produced any one of the active mutant Δ^9 -18:0-ACP desaturases of the invention under examination in this case. While one of skill in the art may be motivated to substitute the amino acids, one of skill in the art would have NO expectation that substituting any amino acid for the native amino acid would work. Further, while one of skill may have been motivated and taught which amino acids are candidates for substitution in an expectation of altering the activity, the cited reference is merely a motivation to try substituting the candidate residues.

An additional consideration should be given to the selection methods of US Patent No. 6,686,186 from which this application ultimately claims priority. Without the methods of the

cited parent patent even a person highly skilled in the art and even a highly motivated person of skill in the art would have been forced to meticulously and serially substitute each and every amino acid for the residues 114, 117, 118, 179, 181 and 188 and do so for each position in combination with the substitutions in every other position. Minimally one can calculate that this would be 6^{19} (more than 1×10^9) variants (19 possible substitutions for each of positions 114, 117, 118, 179, 181 and 188 by the six-way in combination with every other substitution) for which one would need to produce the mutated DNA, make the expression constructs, test the expression, isolate the produced enzyme (if any) and test the activity of such enzymes such as were produced. It should be clear that the motivation to try would create a situation calling for undue experimentation to arrive at the collection of mutants claimed in this application. Further, this does not even take into consideration that the Cahoon et al. reference cited by the Examiner includes the suggestion that residues 180, 117, 189, 200, 205, 206 and 207 may also be candidates for producing the mutant desaturase. Being obvious to try to achieve an outcome does not, in an unpredictable art such as this, create a basis for rejection for obviousness. Therefore, the Agent for the Applicants respectfully requests reconsideration and withdrawal of the 35 USC 103 rejection.

In further support of the above remarks made in support of withdrawal of the rejection, and in consideration of the Examiner's statement that "Cahoon et al. do not teach the specifically claimed substitution(s)", the Agent respectfully requests the Examiner review Table I and Figure 5 of the cited reference. In Table I, all characterized mutants were mutants of the Δ^6 -16:0-ACP desaturase to increase its activity on 18:0 substrates. None of the Table I mutants are mutants of the Δ^9 -18:0-ACP desaturase. The only mutant of the Δ^9 -18:0-ACP desaturase characterized in the citation was the double substitution mutant Leu for Phe at 118 in combination with Pro for

Ile at 179 (Figure 5). Although a double mutant such as the L118F/P179I double mutant could be considered to be encompassed within the scope of Claim 1 preamble wherein the claim encompasses mutant desaturase-encoding DNA “having one or more amino acid substitutions” the Examiner should note that substitution of Phe (F) for residue Leu (L) 118 is NOT claimed and substitution of Ile (I) for Pro (P) 179 is NOT claimed in the mutants of the claims presently under examination. Therefore the specific mutants of the present claims are not obvious based upon the teachings of the cited Cahoon et al. reference. Again, the Agent for the Applicants respectfully urges the withdrawal of the rejection under 35 USC § 103 (a).

8. Double Patenting:

The Examiner rejected the claims of the pending case, invoking nonstatutory double patenting, noting that a timely filed terminal disclaimer in compliance with 37CFR 1.321 may be used to overcome such nonstatutory double patenting ground for rejection, provided the conflicting application or patent is shown to be commonly owned with this application (37 CFR 1.130(b)).

In accordance, the applicants have included herein such a Terminal Disclaimer. The claims amended herein, those as originally filed and those newly added are, accordingly, set to expire upon the expiration of the referenced patents. The Agent for the Applicant respectfully submits that the herein submitted Terminal Disclaimer provides sufficient grounds for reversal of the double patenting rejection and solicits such from the Examiner.

Additional Remarks:

New Claims:

New claims 54 through 62 have been added. Claim 54 corresponds to originally filed claims 2 through 9, but written in independent form, and claim 55 corresponds to claim 10, but depending from Claim 54. Claims 56 – 62 restate the substance of originally filed claims 11 -17.

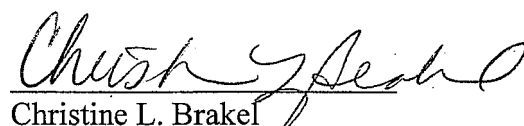
The new claims contain no new matter.

Fee Corrections:

The Agent for the Applicants wishes to draw the Examiner's attention to the correction of fees for the present application, a copy of which is attached to this paper.

Based upon the above amendments, remarks and requests, the Applicants submit that the present application is now in condition for allowance and solicit a timely notice thereof.

Respectfully submitted,



Christine L. Brakel
Agent for Applicants
Registration No. 45,772

Date: April 13, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: **John Shanklin, et al.**

Application No.: **10/822,370** Examiner: **T. Saidha**

Filing Date: **April 12, 2004** Art Unit: **1652**

Confirmation No.: **2864** Attorney Docket No.: **BSA 04-11**

Title: **MUTANT FATTY ACID DESATURASE AND METHODS
FOR DIRECTED MUTAGENESIS**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

FILING FEE CORRECTION

On the date of filing, the Applicant noted that the following amount was to be charged to Deposit Account 02-3977:

Utility Filing Fee	\$385
53 total claims (33 excess X \$9)	\$297
8 Independent Claims (5 excess X \$43)	\$215
<u>Multiple Dependent Claim(s)</u>	<u>\$140</u>
Total	\$1,037

It has come to our attention that this was calculated incorrectly. The correct calculation follows.

Correct calculation based on application as filed:

Utility Filing Fee	\$385
62 total claims (42 excess X \$9)	\$378
8 Independent Claims (5 excess X \$43)	\$215
<u>Multiple Dependent Claim(s)</u>	<u>\$145</u>
Total	\$1,123

Amount charged to Deposit Account 02-3977 by The Office on 4/24/2004: \$899.00

Deficiency owed: \$224

The practitioner hereby avers that Applicant's payment errors were made without deceptive intent and request their excusal.

Please charge the amount of \$224.00 to Deposit Account 023977. If any additional fees are due or any overpayment has been made, please charge or credit Deposit Account No. 02-3977 for such sum.

April 13, 2007

Registration No.:45,772

Telephone No.:(631) 344-7134

Christine L. Brakel

Signature of Practitioner

Christine L. Brakel

(Type Name of Practitioner)

Brookhaven National Laboratory
Office of Intellectual Property & Sponsored
Research
PO Box 5000
Upton, New York 11973-5000

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

04/14/2004 YPOLITE1 00000017 023977 10822370

01 FC:2001	385.00 DA
02 FC:2202	369.00 DA
03 FC:2203	145.00 DA

899.00

PTO-1556
(5/87)

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 2003

Application or PCT Number

10822370

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	59	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	61 minus 20 =	* 41
INDEPENDENT CLAIMS	2 minus 3 =	* 9
MULTIPLE DEPENDENT CLAIM PRESENT <input checked="" type="checkbox"/>		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

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AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
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FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

SMALL ENTITY TYPE ☒

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	385.00
X\$ 9=	364
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BASIC FEE	770.00
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RATE	ADDITIONAL FEE
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**MULTIPLE DEPENDENT CLAIM
FEE CALCULATION SHEET**

SERIAL NO. **10822370**
APPLICANT(S)

FILED DATE **4-12-04**

CLAIMS

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Index of Claims



Application/Control No.

10/822,370

Examiner

Tekchand Saidha

Applicant(s)/Patent under Reexamination

SHANKLIN ET AL.

Art Unit

1652

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date											
Final	Original	10/23/06											
	1	✓											
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John Shanklin, et al.

Application No.: 10/822,370

Examiner: T. Saidha

Filing Date: April 12, 2004

Art Unit: 1652

Confirmation No.: 2864

Attorney Docket No.: BSA 04-11

**Title: MUTANT FATTY ACID DESATURASE AND METHODS FOR DIRECTED
MUTAGENESIS**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FEE WORKSHEET

Filed As Small Entity.

Filing Deficiency owed by Applicant

\$224 (TOTAL)